Clinical trial results:
Continuing Treatment for Subjects Who Have Participated on a Prior Protocol Investigating Dasatinib

Summary

EudraCT number	2014-004278-40
Trial protocol	PL
Global end of trial date	15 May 2022

Results information

Result version number	v1 (current)
This version publication date	30 April 2023
First version publication date	30 April 2023

Trial information

Trial identification

Sponsor protocol code	CA180-597

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02297139
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 July 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this clinical study was to provide dasatinib treatment to participants who have participated on a prior protocol investigating dasatinib and to monitor the safety and tolerability of dasatinib.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 July 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Poland: 16
Worldwide total number of subjects	17
EEA total number of subjects	17

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	9
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

17 participants were treated.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Prostate Cancer

Arm description:

Continuing treatment for prostate cancer participants who have participated on prior protocol CA180-227 investigating dasatinib. Dasatinib tablet administered once a day by mouth.

Arm type	Experimental
Investigational medicinal product name	Dasatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dasatinib tablet administered once a day by mouth

Arm title	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)

Arm description:

Continuing treatment for CP- CML participants who have participated on prior protocols CA180-363 and CA180-056 investigating dasatinib. Dasatinib tablet administered once a day by mouth.

Arm type	Experimental
Investigational medicinal product name	Dasatinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dasatinib tablet administered once a day by mouth

Number of subjects in period 1	Prostate Cancer	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)
Started	1	16
Completed	0	0
Not completed	1	16
Disease progression	-	1

Study drug toxicity	-	4
Maximum clinical benefit	1	-
Other reasons	-	8
Participant request to discontinue study treatment	-	1
Administrative reason by sponsor	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Prostate Cancer
Reporting group description:	
Continuing treatment for prostate cancer participants who have participated on prior protocol CA180-227 investigating dasatinib. Dasatinib tablet administered once a day by mouth.	
Reporting group title	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)
Reporting group description:	
Continuing treatment for CP- CML participants who have participated on prior protocols CA180-363 and CA180-056 investigating dasatinib. Dasatinib tablet administered once a day by mouth.	

Reporting group values	Prostate Cancer	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)	Total
Number of subjects	1	16	17
Age categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	8	9
From 65-84 years	0	8	8
85 years and over	0	0	0
Age Continuous Units: Years			
median	58	64.5	
full range (min-max)	58 to 58	35 to 75	-
Sex: Female, Male Units: Participants			
Female	0	8	8
Male	1	8	9
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	16	16
More than one race	0	0	0
Unknown or Not Reported	1	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	15	15

Unknown or Not Reported	1	1	2

End points

End points reporting groups

Reporting group title	Prostate Cancer
Reporting group description:	
Continuing treatment for prostate cancer participants who have participated on prior protocol CA180-227 investigating dasatinib. Dasatinib tablet administered once a day by mouth.	
Reporting group title	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)
Reporting group description:	
Continuing treatment for CP- CML participants who have participated on prior protocols CA180-363 and CA180-056 investigating dasatinib. Dasatinib tablet administered once a day by mouth.	

Primary: Number of Participants Who Received Dasatinib Treatment

End point title	Number of Participants Who Received Dasatinib Treatment[1]
End point description:	
Number of participants who received dasatinib treatment for prostate cancer and chronic phase chronic myeloid leukemia who had also participated on prior protocols CA180-227, CA180-363 and CA180-056 investigating dasatinib. Dasatinib tablet administered once a day by mouth.	
End point type	Primary
End point timeframe:	
From first dose on this study (CA180-597) to last dose on this study (up to approximately 76 months)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics planned for this endpoint.

End point values	Prostate Cancer	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	16		
Units: Participants	1	16		

Statistical analyses

No statistical analyses for this end point

Primary: Duration of Treatment

End point title	Duration of Treatment[2]
End point description:	
Duration of treatment for participants who received dasatinib treatment for prostate cancer and chronic phase chronic myeloid leukemia who had also participated on prior protocols CA180-227, CA180-363 and CA180-056 investigating dasatinib. Dasatinib tablet administered once a day by mouth.	
End point type	Primary
End point timeframe:	
From first dose on this study (CA180-597) to last dose on this study (up to approximately 76 months)	

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics planned for this endpoint.

End point values	Prostate Cancer	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	16		
Units: Months				
median (full range (min-max))	25.3 (25.3 to 25.3)	55.9 (4.0 to 75.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Adverse Events

End point title	Number of Participants with Serious Adverse Events

End point description:

Number of participants with serious adverse events (SAEs). SAE is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is an important medical event.

End point type	Secondary

End point timeframe:

From first dose on this study (CA180-597) to 30 days after last dose of study therapy (up to approximately 77 months)

End point values	Prostate Cancer	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	16		
Units: Participants	0	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events

End point title	Number of Participants with Adverse Events

End point description:

Number of Participants with Adverse Events (AEs). An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug.

End point type	Secondary

End point timeframe:

From first dose on this study (CA180-597) to 30 days after last dose of study therapy (up to approximately 77 months)

End point values	Prostate Cancer	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	16		
Units: Participants	1	15		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and NSAEs assessed from first dose to 30 days after last dose (up to approximately 77 months). Participants were assessed for all-cause mortality from their first dose until their study completion (up to approximately 82 months).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)

Reporting group description:

Continuing treatment for CP- CML participants who have participated on prior protocols CA180-363 and CA180-056 investigating dasatinib. Dasatinib tablet administered once a day by mouth.

Reporting group title	Prostate Cancer

Reporting group description:

Continuing treatment for prostate cancer participants who have participated on prior protocol CA180-227 investigating dasatinib. Dasatinib tablet administered once a day by mouth.

Serious adverse events	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)	Prostate Cancer	
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 16 (50.00%)	0 / 1 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Thyroid neoplasm			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			

subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Hydrothorax			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Chronic Phase - Chronic Myeloid Leukemia (CP-CML)	Prostate Cancer	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 16 (93.75%)	1 / 1 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Thyroid neoplasm			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 16 (37.50%)	0 / 1 (0.00%)	
occurrences (all)	7	0	
Phlebitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Fatigue			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Non-cardiac chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Pyrexia			

subjects affected / exposed	3 / 16 (18.75%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Reproductive system and breast disorders			
Heavy menstrual bleeding			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	6 / 16 (37.50%)	0 / 1 (0.00%)	
occurrences (all)	8	0	
Hydrothorax			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Dyspnoea			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Cough			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Investigations			
Blood testosterone increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Blood pressure increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Mitral valve incompetence			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Supraventricular tachycardia			

subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Cardiac failure			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Angina pectoris			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Tricuspid valve incompetence			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 16 (18.75%)	0 / 1 (0.00%)	
occurrences (all)	4	0	
Iron deficiency anaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Lymphadenopathy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Neutropenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			

subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hyperhidrosis			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Erythema multiforme			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Renal cyst			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Spinal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Arthralgia			
subjects affected / exposed	4 / 16 (25.00%)	0 / 1 (0.00%)	
occurrences (all)	5	0	
Infections and infestations			

Conjunctivitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
COVID-19			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 16 (25.00%)	0 / 1 (0.00%)	
occurrences (all)	5	0	
Pneumonia			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Pharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection			
subjects affected / exposed	2 / 16 (12.50%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Metabolism and nutrition disorders			
Hyperuricaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypercholesterolaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 1 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported